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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,953	11/30/2001	Marion J. Bussemakers	1619.0100000/SRL/AGU	2414

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EXAMINER	
KETTER, JAMES S	

ART UNIT	PAPER NUMBER
1636	9

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Commissioner for Patents

--See attached--

Office Action Summary	Application No.	Applicant(s)	
	09/996,953	BUSSEMAKERS ET AL.	
	Examiner	Art Unit	
	James S. Ketter	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11 and 15* is/are rejected.

7)☒ Claim(s) *9,10 and 12-14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

All claims and inventions are hereby **rejoined**. As such, the restriction requirement mailed 11 February 2003 is hereby withdrawn. All pending claims are now under examination.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Verhaegh et al. (U).

Verhaegh et al. teaches, e.g., at the abstract and Figure 1, the genomic sequence of the DD3 gene including the 5' flanking region, showing the same DNA sequence as SEQ ID NO.1 of the instant application. At page 37497, left-hand column, first paragraph of "MATERIALS AND METHODS", it is taught that this and other genomic clones were present in a lambda bacteriophage library, hence vectors comprising the DNA of SEQ ID NO. 1 were taught. At Figure 3, transcriptional fusions of the DD3 promoter region with a therapeutic, heterologous gene (human growth hormone) are taught.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Bussemakers et al. (AR, of record).

At Figure 3, Bussemakers et al. teaches the genomic map of DD3, including the upstream region including the SEQ ID NO. 1 of the instant application (located within the EcoRi-HinDIII fragment containing exon 1.) This molecule inherently contains the nucleic acids of instant claims 1 and 2. At page 5976, left-hand column, second and third full paragraphs, it is taught that this molcule was found in a genomic library in a lambda bacteriophage clone, which meets the limitations of instant claims 3 and 4. Inhrently, such clones are harbored in E. coli cells, thus meeting the limitations of instant claims 5 and 6.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Verhaegh et al. (U).

At page 37496, right-hand column, last full paragraph, it is taught that DD3 mRNA had been detected as highly expressed correlated with the cell being a prostatic tumor cell. While this disclosure does not particularly teach a method whereby a sample would be tested for such expression, leading to a diagnosis of prostate cancer, it would have been obvious to one of ordinary skill in the art that such a correlation would work both ways, that is, DD3 is taught as being one of the most prostate cancer-specific expression markers extant, and as such, one of ordinary skill would have recognized that detecting high DD3 expression would have correlated back to a diagnosis of prostate cancer. The motivation to have used this correlation this way would have been founded in the fact of this correlation, in view of the well-known use of cancer markers in the diagnostic art.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bussemakers et al. (AR).

At page 5975, Bussemakers et al teaches that the expression of DD3 is limited to the prostate and thus "DD3 is one of the most prostate cancer-specific genes yet described, and provides a promising tool for the early diagnosis of prostate cancer..." Figure 1 describes a northern blot method of comparing expression of DD3 to the cancer state of prostate cells.

While Bussemakers et al. does not teach that this northern blot method is a diagnostic method of the type in the instant claim, it would have been obvious to one of ordinary skill in the art to have used the method on samples of prostate tissue from a patient to diagnose prostate cancer, in view of the suggestion at page 5975, noted above. Such suggestion would have provided motivation to have taken data from a northern blot method run from patient RNA and to have predicted the presence or absence of prostate cancer, especially as DD3 is referred to as a "promising tool" for such diagnosis.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 8 recites "an agent capable of modulating a transcriptional activity of" the nucleic acid comprising the recited portion of DD3 promoter. However, the specification only sets forth a subgenus of such possible agents, i.e., antisense molecules. Furthermore, no example of an antisense molecule is set forth by sequence or by nucleotide positions it covers in the gene. The total genus of agents is potentially vast, encompassing molecules of all types and sizes. No structure-function correlation is taught in the specification or the prior art which would permit

one of skill in the art to know the structures of such agents a priori. With respect to the antisense subgenus, no guidance for selection of particular regions of the gene to cover have been set forth. The antisense art is not sufficiently predictable in its structure-function theory to permit one of skill to view a target gene sequence and then know which potential antisense molecules will inhibit transcription. As such, one of skill would not have recognized that Applicants were in possession of the antisense subgenus of agents as recited in the claim, let alone the larger genus of any molecule types.

Claims 9, 10 and 12-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Certain papers related to this application may be submitted directly to the Examiner by facsimile transmission at (703) 746-5155. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR ' 1.6(d)). To send the facsimile to the Art Unit instead, the Art Unit 1636 Fax number is (703) 305-7939. NOTE: If Applicant does submit a paper by fax to this number, the Examiner must be notified promptly, to ensure matching of the faxed paper to the application file, and the original signed copy should be retained by Applicant or Applicant's representative. (703) 308-4242 or (703) 305-3014 may be used without notification of the

Examiner, with such faxed papers being handled in the manner of mailed responses. Applicant is encouraged to use the latter two fax numbers unless immediate action by the Examiner is required, e.g., during discussions of claim language for allowable subject matter. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (703) 308-1169. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Jsk
August 22, 2003

JAMES KETTER
PRIMARY EXAMINER